SETTLEMENT AGREEMENT BETWEEN STATE BOARD OF PHARMACY AND ALBERS MEDICAL DISTRIBUTORS, INC.

Albers Medical Distributors, Inc. ("Licensee") and the State Board of Pharmacy ("Board") enter into this settlement agreement for the purpose of resolving the question of whether Licensee's license as a drug distributor will be subject to discipline.

Pursuant to the terms of § 536.060, RSMo,[1] the parties hereto waive the right to a hearing by the Administrative Hearing Commission of the State of Missouri and, additionally, the right to a disciplinary hearing before the Board under § 621.110, RSMo, and stipulate and agree that a final disposition of this matter may be effectuated as described below.

Licensee acknowledges that it understands the various rights and privileges afforded it by law, including the right to a hearing of the charges against it; the right to appear and be represented by legal counsel; the right to have all charges against it proven upon the record by competent and substantial evidence; the right to cross-examine any witnesses appearing at the hearing against it; the right to a decision upon the record by a fair and impartial administrative hearing commissioner concerning the charges pending against it and, subsequently, the right to a disciplinary hearing before the Board at which time it may present evidence in mitigation of discipline; and the right to recover attorney's fees incurred in defending this action against its license. Being aware of these rights provided to Licensee by operation of law, Licensee knowingly and voluntarily waives each and every one of these

[1]All statutory references are to the 2000 Revised Statutes of Missouri, as amended, unless otherwise stated.

rights and freely enters into this settlement agreement and agrees to abide by the terms of this document, as they pertain to it.

Licensee acknowledges that it has received a copy of the investigative report and other documents relied upon by the Board in determining there was cause for discipline, along with citations to law and/or regulations the Board believes were violated. For the purpose of settling this dispute, Licensee stipulates that the factual allegations contained in this settlement agreement are true and stipulates with the Board that Licensee's drug distributor license, License No. 900306, is subject to disciplinary action by the Board in accordance with the provisions of Chapter 621 and 338, RSMo.

Joint Stipulation of Facts

1. The Missouri Board of Pharmacy ("Board") is an agency of the State of Missouri created pursuant to § 338.140, RSMo for the purpose of executing and enforcing the provisions of Chapter 338, RSMo.

2. At all relevant times herein, Respondent Albers Medical Distributors, Inc. ("Licensee") was licensed by the Board as a drug distributor, License No. 900306 ("license"). Licensee's Missouri drug distributor license was current and active at all times relevant herein.

3. At all times relevant herein, Douglas C. Albers ("Albers"), a registered pharmacist licensed by the Board, License No. 029838, owned, operated, and served as control person of Licensee.

4. At all times relevant herein, Licensee utilized the services of a pharmaceutical broker, OTS Sales, to purchase and sell pharmaceutical products.

5. Beginning in 2000, the Board advised Licensee ("Board's notice") that it could not purchase pharmaceuticals from licensed out-of-state distributors unless the distributor was also licensed in Missouri. Licensee advised OTS Sales accordingly.

6. In June 2001, the Food and Drug Administration ("FDA") issued a counterfeit/misbranded drug notice ("FDA notice") concerning Neupogen, Lot No. P000954.

7. The FDA also notified Licensee of counterfeit Neupogen purchased and distributed by Licensee through OTS Sales.

8. Neupogen is an injectable human granulocyte colony stimulating factor manufactured by Amgen, Inc.

9. Neupogen is a drug approved for use, among other things, in stimulating the production of white blood cells in order to decrease the incidence of infections in persons with lowered immune systems.

10. Neupogen is a drug within the meaning of 21 U.S.C. § 321(g)(1).

11. Neupogen is a drug within the meaning of § 195.010(14), RSMo.

12. In September 2001, despite the Board's and FDA notice, Licensee, through OTS Sales, purchased two 10 vial boxes of counterfeit and misbranded Neupogen from MedRx.

13. MedRX was a non-Missouri licensed drug distributor.

14. On September 25, 2001, despite the Board's and FDA notice, Licensee, through OTS Sales, sold to Actsys Medical, Inc. ("Actsys") the two 10 vial boxes of the counterfeit and misbranded Neupogen it had purchased from MedRX earlier that month.

15. Actsys was misled into believing it was purchasing non-counterfeit Neupogen.

16. Despite the Board's notice, Licensee did not take sufficient investigatory or precautionary steps to prevent itself or OTS Sales from purchasing drugs from a non-Missouri licensed drug distributor.

17. Despite the FDA notice in June 2001, and despite its prior knowledge of counterfeit and misbranded Neupogen, Licensee did not take sufficient investigatory or precautionary steps to prevent itself or OTS Sales from purchasing and selling counterfeit and misbranded Neupogen in September 2001.

18. As a result of the conduct alleged in paragraphs 1-16, on October 18, 2006, in the United State District Court, Western District of Missouri, Case No, 05-00315-01-CR-W-ODS, Albers pled guilty to: 1) knowingly selling a counterfeit drug, in violation of 21 U.S.C. § 331(i)(3) and 333(a)(2); and 2) knowingly selling a misbranded drug, in violation of 21 U.S.C. § 331(a) and 333(a)(2).

Joint Conclusions of Law

19. 21 U.S.C. § 331, in pertinent part, states as follows:

> The following acts and the causing thereof are prohibited:
>
> (a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.

* * * *

(i)(3) The doing of any act which causes a drug to be a counterfeit drug, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit drug.

20. 20 C.S.R. 2220-5.020, in pertinent part, states as follows:

(1) A "wholesale drug distributor" is defined in section 338.330(3), RSMo. No wholesale drug distributor with physical facilities located in the state of Missouri shall knowingly purchase or receive legend drugs and/or drug related devices from a wholesale drug distributor or pharmacy not licensed or registered by the board. Knowledge of the licensure status of a drug distributor or pharmacy includes, but is not limited to, actual or constructive knowledge. Knowledge of the license status of a drug distributor or pharmacy shall also include, but not be limited to, notification from the board by mail or electronic transmission.

21. Section 338.055, RSMo, in pertinent part, states as follows:

2. The board may cause a complaint to be filed with the administrative hearing commission as provided by chapter 621, RSMo, against any holder of any certificate of registration or authority, permit or license required by this chapter or any person who has failed to renew or has surrendered his certificate of registration or authority, permit or license for any one or any combination of the following causes:

* * * *

(4) Obtaining or attempting to obtain any fee, charge, tuition or other compensation by fraud, deception or misrepresentation;

(5) Incompetency, misconduct, gross negligence, fraud, misrepresentation or dishonesty in the performance of the functions or duties of any profession licensed or regulated by this chapter;

(6) Violation of, or assisting or enabling any person to violate, any provision of this chapter, or of any lawful rule or regulation adopted pursuant to this chapter.

* * * *

(13) Violation of any professional trust or confidence;

(14) Use of any advertisement or solicitation which is false, misleading or deceptive to the general public or persons to whom the advertisement or solicitation is primarily directed;

(15) Violation of the drug laws or rules and regulations of this state, any other state or the federal government[.]

22. Based on the stipulation of facts and conclusions of law cited above, cause exists to discipline Licensee's license pursuant to § 338.055.2(4), (5), (6), (13), (14), and (15), RSMo.

Jointly Agreed Disciplinary Order

Based upon the foregoing, the parties mutually agree and stipulate that the following shall constitute the disciplinary order entered by the Board in this matter under the authority of § 621.045.3, RSMo.

1. Licensee's drug distributor license, License No. 900306 is hereby VOLUNTARILY SURRENDERED. Licensee shall immediately return all indicia of licensure as a drug distributor to the Board. Licensee may not reapply for licensure with the Board for seven (7) years.

2. The parties to this settlement agreement understand that the State Board of Pharmacy will maintain this settlement agreement as an open and public record of the Board as provided in Chapters 334, 610, and 620, RSMo.

3. The terms of this settlement agreement are contractual, legally enforceable, and binding, not merely recital. Except as otherwise contained herein, neither this settlement agreement nor any of its provisions may be changed, waived, discharged, or terminated, except by an instrument in writing signed by the party against whom the enforcement of the change, waiver, discharge, or termination is sought.

4. Licensee hereby waives and releases the Board, its members and any of its employees, agents, or attorneys, including any former Board members, employees, agents, and attorneys, of, or from, any liability, claim, actions, causes of action, fees, costs and expenses, and compensation, including, but not limited to, any claims for attorney's fees and expenses, including any claims pursuant to § 536.087, RSMo, or any claim arising under 42 U.S.C. § 1983, which may be based upon, arise out of, or relate to any of the matters raised in this litigation, or from the negotiation or execution of this settlement agreement. The parties acknowledge that this paragraph is severable from the remaining portions of this settlement agreement in that it survives in perpetuity even in the event that any court of law deems this settlement agreement or any portion thereof void or unenforceable.

5. Licensee understands that it may, either at the time the settlement agreement is signed by all parties, or within fifteen (15) days thereafter, submit the agreement to the

Administrative Hearing Commission for determination that the facts agreed to by the parties constitute grounds for disciplining Licensee's drug distributor license. If Licensee desires the Administrative Hearing Commission to review this agreement, Licensee may submit its request to: Administrative Hearing Commission, Truman State Office Building, Room 640, 301 W. High Street, P.O. Box 1557, Jefferson City, Missouri 65101.

6. If Licensee requests review, this settlement agreement shall become effective on the date the Administrative Hearing Commission issues its order finding that the settlement agreement sets forth cause for disciplining Licensee's license. If Licensee does not request review by the Administrative Hearing Commission, the settlement agreement goes in to effect 15 days after the document is signed by the Executive Director of the Board.

LICENSEE

By:_____
Albers Medical Distributors, Inc.

Date 3.20.09

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